



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0003]

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Cyclosporine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of cyclosporine oral solution, USP (MODIFIED) for the control of feline allergic dermatitis.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141-329 that provides for the use of ATOPICA for Cats (cyclosporine oral solution, USP (MODIFIED)) by veterinary prescription for the control of feline allergic dermatitis in cats at least 6 months of age and weighing at least 3 pounds. The NADA is approved as of August 8, 2011, and 21 CFR 520.522 is amended to reflect the approval.

A summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. In § 520.522, revise paragraphs (a) and (d) to read as follows:

§ 520.522 Cyclosporine.

(a) Specifications--(1) Each cyclosporine capsule, USP (MODIFIED) contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

(2) Each milliliter of cyclosporine oral solution, USP (MODIFIED) contains 100 mg cyclosporine.

* * * * *

(d) Conditions of use--(1) Dogs. Use capsules described in paragraph (a)(1) of this section as follow:

(i) Amount. Administer 5 mg per kilogram (mg/kg) of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(ii) Indications for use. For the control of atopic dermatitis in dogs weighing at least 4 pounds.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Cats. Use the solution described in paragraph (a)(2) of this section as follow:

(i) Amount. Administer 7 mg/kg of body weight orally as a single daily dose for a minimum of 4 to 6 weeks or until resolution of clinical signs. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or twice weekly to maintain the desired therapeutic effect.

(ii) Indications for use. For the control of feline allergic dermatitis in cats at least 6 months of age and weighing at least 3 pounds.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 15, 2011.

Bernadette Dunham,

Director,
Center for Veterinary Medicine.

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